

<b>PRE-APPEAL BRIEF REQUEST FOR REVIEW</b>		Docket Number (Optional)
		4532660/55140
<p>I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to "Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450" [37 CFR 1.8(a)]</p> <p>on _____</p> <p>Signature _____</p> <p>Typed or printed name _____</p>	Application Number	Filed
	10/532,775	10/07/2005
	First Named Inventor Masayoshi Yamaguchi	
	Art Unit 1614	Examiner Raymond J. Henley, III

Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.

This request is being filed with a notice of appeal.

The review is requested for the reason(s) stated on the attached sheet(s).

Note: No more than five (5) pages may be provided.

I am the

applicant/inventor.

assignee of record of the entire interest.  
See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed.  
(Form PTO/SB/96)

attorney or agent of record.  
Registration number 31025

attorney or agent acting under 37 CFR 1.34.  
Registration number if acting under 37 CFR 1.34 \_\_\_\_\_

/kentaherink/

Signature

Kent A. Herink

Typed or printed name

515-288-2500

Telephone number

August 17, 2010

Date

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required.  
Submit multiple forms if more than one signature is required, see below\*.



\*Total of 1 forms are submitted.

This collection of information is required by 35 U.S.C. 132. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11, 1.14 and 41.6. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of )  
Masayoshi Yamaguchi ) Group Art Unit 1614  
Serial No. 10/532,775 )  
Filed: October 7, 2005 )  
For: Osteogenesis Promoter Containing ) Examiner: Raymond J. Henley, III  
Beta-Cryptoxanthin as the Active )  
Ingredient )

**STATEMENT IN SUPPORT OF PRE-APPEAL REQUEST FORM**

Independent claim 19 recites:

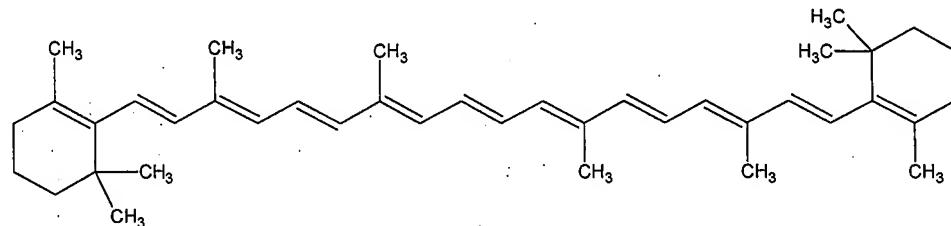
19. A method of ameliorating bone loss problems associated with aging in a person in need thereof, comprising administering to the person in need thereof an amount of purified **β-cryptoxanthin** effective to ameliorate the bone loss problems associated with aging. (Emphasis added.)

All of the claims recite methods utilizing β-cryptoxanthin.

In the Office Action mailed May 17, 2010, claims 19, 21, 22, 24, 25 and 27 are rejected under 35 U.S.C. Section 102(b) as being anticipated by Shlyankevich (U.S. Patent No. 5,424,331). The Patent Office states (page 3):

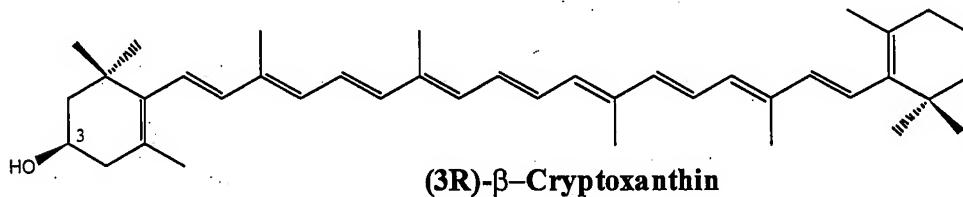
“Shlyankevich teaches a method for treating osteoporosis, (a.k.a. a disease of decreased osteogenesis), which comprises administering to a patient in need thereof an effective amount of **beta-carotene**, (a.k.a. **beta-cryptoxanthin**) which may be in amounts of 6 mg or 20 mg (see the abstract, col 4, lines 24-31; and Examples 1 and 3).” (Emphasis added.)

The Patent Office has made a clear error. Beta-carotene and beta-cryptoxanthin are distinct compounds with distinct properties; beta-carotene is not "also known as" beta-cryptoxanthin. Beta-carotene has the molecular formula C<sub>40</sub>H<sub>56</sub>, a molecular weight of 536.88 and a CAS Registry No. of 7235-40-7. The structure of beta-carotene is below:



**B-Carotene**

Beta-cryptoxanthin has the molecular formula C<sub>40</sub>H<sub>56</sub>O, a molecular weight of 552.88 and a CAS Registry No. of 472-70-8. The structure of beta-cryptoxanthin is below:



Beta-carotene is a carotenoid that is a precursor of Vitamin A, sometimes referred to as a pro-Vitamin A. Vitamin A has been shown to increase the risk of fractures among women (Claire-Juvera, et al., Vitamin A and Retinol intakes and the risk of fractures among participants of the Women's Health Initiative Observational Study, *Am J Clin Nutr* 2009; 89:323-30). Beta-cryptoxanthin is an oxygenated carotenoid, i.e., a xanthophyll, and not a carotene. The presence of the oxygen moiety changes the polarity of the molecule and its biological properties.

It is well known in the art that these are distinct molecules with distinct biological properties. A reference which teaches properties or uses of beta-carotene cannot anticipate the properties or uses of beta-cryptoxanthin. For this reason, it is respectfully requested that the Office Action mailed May 17, 2010, be withdrawn and the application passed to allowance.

Respectfully submitted,

Date: August 17, 2010

/kentaherink/

Kent A. Herink

Registration No. 31025

DAVIS, BROWN, KOEHN,

SHORS & ROBERTS, P.C.

215 10th Street, Suite 1300

Des Moines, Iowa 50309

Telephone: (515) 288-2500

ATTORNEYS FOR APPLICANT